

REMARKS

Claims 14, 15, 17-24, 34-38, 40-43, 49-51, 55-65, and 67-71 are pending. Support for new claims 70 and 71 can be found at least at Example 1, pages 24-27. In support of the remarks and arguments stated *infra*, Applicants have submitted herewith the Declaration of Sean Farmer under 37 C.F.R. §1.132 ("Farmer Declaration"). No new matter has been added.

35 U.S.C. § 112, first paragraph - written description

Claims 14, 15, 17-24, 34-38, 41-43, 49-51, 55-65, and 67-69 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the as-filed specification fails to describe a method of *in vivo* treating yeast and fungal infections by topically applying *Bacillus coagulans* strain 31284 to skin or to mucous membrane. (See Office Action at page 2.) The Examiner states, "[t]he as-filed specification only describes compositions with the cells belonging to some generic representative of the species of *Bacillus coagulans* (page 27-28; formulation 1 and 4) as intended for control fungal and yeasts infections (examples 4, 5, and 7 at pages 29, 31, and 33)." (Office Action at page 2.)

To satisfy the written description requirement, an Applicant must convey with reasonable clarity to those skilled in the art as of the filing date that he or she was in possession of the invention as claimed, *i.e.*, that the disclosure must reasonably convey to the artisan that the inventor has possession of the invention as claimed (MPEP at 2163.02).

Applicants submit that this written description rejection is inappropriate as the Examiner's comments are directed to lack of enablement. As such, Applicants will address the Examiner's rejections in the context of lack of enablement.

35 U.S.C. § 112, first paragraph - enablement

Claims 14-24, 34-43, and 49-69 are rejected under 35 U.S.C. § 112, first paragraph lack of enablement. (See Office Action at page 3.) In applying this rejection, the Examiner has focused upon five factors summarized by *In re Wands*, 858 F.2d 731 (1988), the scope of the claims, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability of the art, and the amount of experimentation required to enable one skilled in the art to practice the claimed invention. (See Office action at page 4.) This rejection is traversed.

The Examiner has indicated that the breath of the claims is directed to a method for inhibiting yeast and/or fungal infections including vaginal infections by applying topically to skin or mucous membrane probiotic compositions with *Bacillus coagulans* strain ATCC# 31284. (See Office action at page 4.) According to the Examiner, the specification only discloses generic doses and generic protocols of topical administration of generic representatives of the species of *Bacillus coagulans*. (See Office Action at page 4.) Applicants disagree.

The claims specifically require *Bacillus coagulans* Hammer (ATCC# 31284). The specification states, “[t]he results described herein were obtained with *B. coagulans* Hammer obtained from the American Type Culture Collection (ATCC# 31284) which was grown as described herein and stored in lyophilized aliquots at -20°C.” (Specification at page 12, lines 6-8.) Exemplary formulations are described in detail throughout the specification (*e.g.*, page 27, lines 16, 23 and 30; page 28, line 8; page 30, line 9 to page 31, line 5; page 31, line 12 to page 32, line 3; page 32, lines 4-14; page 32, line 23 to page 33, line 2; page 33, lines 15-22; page 34, lines 6-12; page 35, lines 21-27; page 36, lines 8-11 and 15-18; and page 37, lines 8-9). In fact, specific ranges and absolute amounts of bacteria or spores to be used in the claimed methods are described in numerous examples. For this reason, an ordinary practitioner would have no difficulty carrying out the claimed methods.

The Examiner has indicated that the specification only discloses *in vitro* assays of antimicrobial activity of *Bacillus coagulans* ATCC# 31284. The Examiner further states that no animals were used as *in vivo* model systems for inhibiting or treating yeast and/or fungal infections including vaginal infections. (See Office Action at page 5.) As noted by the Examiner, the as-filed specification discloses the use of *Bacillus coagulans* Hammer (ATCC# 31284) to inhibit infections of *Trichophyton* species and *Candida* species. (See, *e.g.*, Example 1, pages 24-27.) These data demonstrate the inhibitory effectiveness of the *Bacillus coagulans* Hammer (ATCC# 31284). Moreover, *Bacillus coagulans* Hammer (ATCC# 31284) was surprisingly effective at inhibiting the growth of *Candida albicans*, *Candida glabrata*, and *Candida tropicalis*. (See Farmer Declaration at ¶ 6.) (See Farmer Declaration at Appendix).

As stated in the July 10, 2006 Response, a zone of inhibition of microbial growth on a plate is a reliable indicator of growth inhibition on another surface, *i.e.* skin or mucous membrane of a mammal. The data was obtained using an art-recognized assay system. The Examiner has provided no evidence or reason to believe that this assay would not be indicative of

activity of the bacteria on skin or mucous membrane. Moreover, animal data or clinical data is not a requirement of § 112.

According to the MPEP, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. (See MPEP § 2107.03.) If the art is such that a model is recognized as correlating to a specific condition, then the model should be accepted as a correlation unless the Examiner has evidence that the model does not correlate. (See MPEP s 2164.02.) Rigorous or exact correlation is not required. Merely a reasonable correlation based on the evidence as a whole is sufficient. (See *e.g.*, *In re Brana*, 34 USPQ2d 1436 (1995)). The *in vitro* data disclosed in the present specification adequately demonstrate the capability of *Bacillus coagulans* Hammer (ATCC# 31284) to inhibit yeast and/or fungal infections on skin or on mucous membrane.

Claim 34 is drawn to a method of inhibiting growth of yeast or fungus by applying a bacterial component consisting of *Bacillus coagulans* Hammer (ATCC# 31284) to a solid surface, contacting the solid surface with the applied *Bacillus coagulans* bacteria thereon to skin or a mucous membrane of a mammal, and allowing the solid surface to contact the skin or mucous membrane for sufficient time to allow initiation of probiotic activity of the *Bacillus coagulans* bacteria to inhibit growth of yeast or fungus or a combination thereof adjacent to or on the skin or mucous membrane.

The as-filed specification discloses the use of *Bacillus coagulans* Hammer (ATCC# 31284) to inhibit infections of *Trichophyton* species and *Candida* species. (See, *e.g.*, Example 1, pages 24-27.) Additionally, *Bacillus coagulans* Hammer (ATCC# 31284) was surprisingly effective at inhibiting the growth of *Candida albicans*, *Candida glabrata*, and *Candida tropicalis*. (See Farmer Declaration at ¶ 6.) Collectively, these data demonstrate the inhibitory effectiveness of the *Bacillus coagulans* Hammer (ATCC# 31284) when applied to a solid surface. Thus, Applicants submit that at least claim 34 (and those that depend therefrom) is enabled by the as-filed specification.

Claims 51, 70, and 71 specifically require that the yeast pathogen is selected from the group consisting of *Candida albicans*, *Candida tropicalis*, and a combination thereof. As stated above, the specification and the Farmer Declaration demonstrate the ability of *Bacillus coagulans*

Hammer (ATCC# 31284) to inhibit both *Candida albicans* and *Candida tropicalis*. Thus, Applicants submit that at least claims 51, 70, and 71 are enabled by the as-filed specification.

For the above-stated reasons, Applicants assert that the methods as presently claimed are predictable and that the level of experimentation left to the skilled practitioner is not undue. Therefore, the pending claims, as amended herein, are fully enabled, and this rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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